OCT 2 6 2009

510(k) SUMMARY K091413

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	May 12, 2009	(updated October 19, 2009)
Device:	Trade Name:	S-Test CHO, S-Test HDL, and S-Test TG Reagent cartridges
	Classification:	Class I
	Common/Classification Names:	Enzymatic esterase-oxidase, cholesterol (21 C.F.R. § 862.1475) Product Code CHH Lipoprotein test system (HDL) (21 C.F.R. § 862.1475) Product Code LBS Lipase hydrolysis/glycerol kinase enzyme triglycerides test system (21 C.F.R. § 862.1705) Product Code CDT
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE plus ISE/Clinical Chemistry System Cholesterol, HDL Cholesterol and Triglycerides Reagents (K931786)	
Device Description:	The S-Test Cholesterol (CHO), S-Test HDL Cholesterol (HDL) and S-Test Triglycerides (TG) reagent cartridges, used with the S40 Clinical Analyzer, are intended for quantitative *in vitro* diagnostic determination of CHO, HDL, and TG concentrations in serum or heparin plasma based on a photometric test measuring the formation of reddish purple complexes in coupled enzymatic reactions.	

Intended Use:	The S-Test Cholesterol Reagent is intended for the quantitative determination of cholesterol concentration in serum or heparin plasma using the S40 Clinical Analyzer. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The S-Test High Density Lipoprotein Reagent is intended for the quantitative determination of HDL concentration in serum or heparin plasma using the S40 Clinical Analyzer. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The S-Test Triglycerides Reagent is intended for the quantitative determination of triglyceride concentration in serum or heparin plasma using the S40 Clinical Analyzer. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.
Technological Characteristics:	The S-Test CHO Reagent is contained in a bi-reagent cartridge. Reagent 1 contains 4-aminoantipyrine, cholesterol esterase, and peroxidase. Reagent 2 contains cholesterol oxidase and N-ethyl-N-sulfobutyl-m-toluidine. The S-Test HDL Reagent is contained in a bi-reagent cartridge. Reagent 1 contains N,N-bis(4-sulfobutyl)-m-toluidine, cholesterol oxidase, peroxidase, and bis (2-hydroxyethyl) iminotris (hydroxymethyl) methane. Reagent 2 contains 4-aminoantipyrine, a surface-active agent, cholesterol esterase, and bis (2-hydroxyethyl) iminotris (hydroxymethyl) methane. The S-Test TG Reagent is contained in a bi-reagent cartridge. Reagent 1 contains Glycerol kinase, glycerol-3-phosphate oxidase, N-ethyl-N-sulfobutyl-m-toluidine, and piperazine-N,N'-bis(2-ethanesulfonic acid). Reagent 2 contains 4-aminoantipyrine, lipoprotein lipase, peroxidase, piperazine-N,N'-bis(2-ethanesulfonic acid).

Performance Data:	S-Test CHO Performance data on the S-Test CHO included precision, accuracy, detection limit, and matrix comparison data. Precision: In testing three CHO levels for 22 days, the within-run CV ranged from 0.9% to 1.6%, and total CV ranged from 2.2% to 2.6%. In precision studies at three separate Physician Office Laboratory (POL) sites and in-house over five days, the within-run CV ranged from 0.3% to 2.0% and total CV ranged from 0.7% to 2.0%. Accuracy: In a correlation study, 98 samples with CHO values ranging from 31 to 335 mg/dL were assayed on the S40 Clinical Analyzer using S-Test CHO (y) and a comparative method (x). Least-squares regression analysis yielded a correlation coefficient of 0.983, a standard error estimate of 11.3, a confidence interval slope of 0.942 to 1.014, and a confidence interval intercept of -3.8 to 10.8. In patient correlation studies at three separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients of 0.9585 to 0.9969, standard error estimates of 4.8 to 16.7, confidence interval slopes of 0.868 to 1.056, and a confidence interval intercepts of -15.7 to 16.2. Detection Limit: The detection limit was 7 mg/dL. Serum vs. Plasma: A study was performed by running CHO determinations on 29 paired samples drawn from the same patients in serum and heparin plasma tubes. The use of plasma was confirmed in a matrix comparison study. The means for serum (149 mg/dL) and plasma (147 mg/dL) differed by less than the tolerance limit of ±5%. The range in serum was 22 to 249 mg/dL. S-Test HDL Performance data on the S-Test HDL included precision, accuracy, detection limit, and matrix comparison data. Precision: In testing conducted at three HDL levels for 23 days, the within-run CV ranged from 2.0% to 2.8%, and total CV ranged from 6.0% to 6.5%. In precision studies at three separate POL sites and in-house over five days, the within-run CV ranged from 1.2% to 2.8% and total CV ranged from 1.2% to 3.4%. Accuracy: In the correlation study, 94 samples with HDL values ranging from 15 to 116 mg/dL were assayed on the S40 Clinical Analyzer using S-Test HDL (y) and a comparative method (x). Least-squares regression analysis yielded a correlation coefficient of 0.970, a standard error estimate of 4.8, a confidence interval slope of 0.923 to 1.022, and a confidence interval intercept of -0.5 to 5.2. In patient correlation studies at three separate POL sites using the S40 Clinical

	Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients of 0.9696 to 0.9957 standard error estimates of 1.7 to 4.7, confidence interval slopes of 0.879 to 1.020, and a confidence interval intercepts of -0.7 to 9.0. Detection Limit: The detection limit was 6 mg/dL. Serum vs. Plasma: A study was performed by running HDL determinations on 36 paired samples drawn from the same patients in serum and heparin plasma tubes. The use of plasma was confirmed in a matrix comparison study using the paired t-test for means: Range: 14 to 124 mg/dL (serum), t-Statistic = 0.40, t-Critical value 2.03 at $\alpha = 0.05$, not statistically significant. S-Test TG Performance data on the S-Test TG included precision, accuracy, detection limit, and matrix comparison data. Precision: In testing conducted at three TG levels for 22 days, the within-run CV ranged from 3.3% to 4.1%, and total CV ranged from 3.8% to 4.3%. In precision studies at three separate POL sites and in-house over five days, the within-run CV ranged from 0.5% to 3.9% and total CV ranged from 0.6% to 3.9%. Accuracy: In the correlation study, 87 samples with TG values ranging from 24 to 584 mg/dL were assayed on the S40 Clinical Analyzer using S-Test TG (y) and a comparative method (x). Least-squares regression analysis yielded a correlation coefficient of 0.997, a standard error estimate of 8.7, a confidence interval slope of 1.049 to 1.088, and a confidence interval intercept of -21.2 to -13.7. In patient correlation studies at three separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients of 0.9958 to 0.9990, standard error estimates of 6.6 to 11.9, confidence interval slopes of 0.940 to 1.084, and a confidence interval intercepts of -19.0 to 2.9. Detection Limit: The detection limit was 12 mg/dL. Serum vs. Plasma: A study was performed by running TG determinations on 30 paired samples drawn from the same patients in serum and heparin plasma tubes. The use of plasma was confirmed in a matrix comparison study using the paired t-test for means: Range: 36 to 572 mg/dL (serum), t-Statistic = 2.04, t-Critical value 2.05 at $\alpha = 0.05$, not statistically significant.
Conclusions:	Based on the foregoing data, the devices are safe and effective. These data also indicate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Alfa Wassermann, Inc.
c/o Hyman Katz, PhD
Vice President, Quality and Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

OCT 2 6 2009

Re: k091413
Trade Name: S-Test Cholesterol (CHO), S-Test High Density Lipoprotein Cholesterol (HDL), S-Test Triglycerides (TG)
Regulation Number: 21 CFR §862.1175
Regulation Name: Cholesterol (total) test system.
Regulatory Class: Class I, meets limitation of exemption 862.9 (c)(4) and (c)(9)
Product Codes: CHH, LBS, CDT
Dated: October 19, 2009
Received: October 21, 2009

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k091413

Device Name: S-Test Cholesterol (CHO)

Indication For Use: The S-Test Cholesterol Reagent is intended for the quantitative determination of cholesterol concentration in serum or heparin plasma using the S40 Clinical Analyzer. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091413

Indication for Use

510(k) Number (if known): k091413

Device Name: S-Test High Density Lipoprotein Cholesterol (HDL)

Indication For Use: The S-Test High Density Lipoprotein Reagent is intended for the quantitative determination of HDL concentration in serum or heparin plasma using the S40 Clinical Analyzer. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091413

Indication for Use

510(k) Number (if known): k091413

Device Name: S-Test Triglycerides (TG)

Indication For Use: The S-Test Triglycerides Reagent is intended for the quantitative determination of triglyceride concentration in serum or heparin plasma using the S40 Clinical Analyzer. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Carol C Benson

Division Sign-Off
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